United States Court of Appeals

for the Second Circuit

BRIEF FOR APPELLEE

Affidavit

76-6135

To be argued by
NAOMI REICE BUCHWALD

United States Court of Appeals
FOR THE SECOND CIRCUIT

Docket No. 76-6135

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THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,
Plaintiffs-Appellants,

—v.—

F. DAVID MATHEWS, Secretary of Health, Education and Welfare and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR DEFENDANTS-APPELLEES

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BRIEF FOR DEFENDANTS-APPELLEES

Statement of Issues

1. Were the proceedings before the District Court in accordance with the remand direction of this Court?

2. Did the District Court properly find that the Commissioner of Food and Drugs acted rationally, and not arbitrarily and capriciously, in classifying vitamin A preparations in excess of 10,000 international units ("IU") and vitamin D preparations in excess of 400 IU as drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act?

Statement of the Case

This is the third time this case has been before this Court. The Honorable Marvin E. Frankel, United States District Judge, Southern District of New York, initially denied a preliminary injunction against the regulations pending judicial review and this Court affirmed that denial. 366 F. Supp. 1341 (S.D.N.Y. 1973), *aff'd*, 491 F.2d 845 (2d Cir. 1973). Thus, the regulations at issue in this case have been in effect and enforced by FDA since October 1, 1973. (396a). Thereafter, Judge Frankel reviewed the regulations on the merits and granted FDA's motion for summary judgment. 376 F. Supp. 142 (S.D. N.Y. 1974). On plaintiffs' appeal, this Court sustained most of Judge Frankel's decision in an opinion written by Judge Mansfield and dated February 3, 1975. 512 F.2d 688, *cert. denied*, — U.S. —, 94 S.Ct. 44 (1974).*

However, this Court remanded this case to the District Court for "a greater inquiry" (313a) into the question of whether the Food and Drug Administration ("FDA") had properly deemed vitamins A and D at the levels regulated to be drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(g), in light of this Court's decision in *National Nutritional Foods Association* v. *FDA*, 504 F.2d 761 (2d Cir. 1974) ("*NNFA* v. *FDA*"), which was decided subsequent to Judge Frankel's earlier grant of summary judgment to the FDA (282a-302a).

After proceedings in accordance with this Court's decision of February 3, 1975, Judge Frankel rendered an

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* For clarity and simplicity all subsequent references to this decision will be to the pages of the Joint Appendix where the now published decision has been reproduced. For the same reason, at certain times hereafter this decision will be referred to as Judge Mansfield's decision.

opinion and order on July 2, 1976, dismissing the complaint. It is that decision, reported at 418 F. Supp. 394, from which this appeal is taken. Plaintiffs-appellants are The National Nutritional Foods Association and Solgar Co., Inc. (a trade association of manufacturers, wholesalers and retailers of vitamin preparations and a member manufacturer) (3a).

This Court's direction to the District Court was as follows:

> Accordingly we remand the case to the district court with directions to conduct an *Overton*-type hearing (including such affidavits or testimony as to the Commissioner's reasoning as the court deems necessary) for the purpose of determining whether, upon the entire administrative record before the Commissioner, which the court should scrutinize, Silva v. Lynn, 482 F.2d 1282 (1st Cir. 1973), the Commissioner acted rationally in classifying the higher Vitamin A and D dosage levels as a "drug" within the meaning of § 201(g) of the Act, 21 U.S.C. § 321(g). (314a).

Additional guidance on the procedure the District Court was to follow on remand may be gleaned from another portion of this Court's decision:

> A failure of the agency adequately to explain its actions is not a warrant to the district court to conduct a *de novo* evidentiary hearing, Camp v. Pitts, *supra*. "[T]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." 411 U.S. at 142, 93 S.Ct. at 1244. Instead, the remedy under these circumstances is "to obtain from the agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision

> as may prove necessary." *Id.* at 143, 93 S.Ct. at 1244; *cf.* Kennecott Copper Corp. v. EPA, *supra.* (312a).

The order of remand was strictly limited to the threshold question of whether at the regulated levels vitamins A and D were properly deemed by FDA to be "drugs". The Court held that if they were "drugs" the classification of these higher dosages as "prescription drugs" was not "irrational or arbitrary" (315a). Accordingly, this Court concluded:

> If the district court concludes that the Commissioner acted rationally, the regulations may be upheld and the order granting summary judgment should stand. (314a).

Plaintiff manufacturers argue that this Court's decision of February 3, 1976 was a holding that the existing agency record was inadequate to sustain the vitamin A and D regulations (Appellants' brief at 9, 38). We do not believe that this Court so held. Rather, this Court was confronted with a new issue on appeal, one which had not been presented to the District Court for briefing and examination. At most, we believe that this Court's opinion could be read as an indication that appellate review of the extensive administrative record without benefit of briefs addressed to that record in light of the intervening decision in *NNFA* v. *FDA*, 504 F.2d 791, did not answer the issues raised thereby.

Judge Mansfield expressed concern that the District Court might not have given sufficient attention to the issue of whether vitamin A and D preparations at the regulated level were properly deemed by FDA to be "drugs". This Court remanded the case for more thorough scrutiny by the District Court of the Commis-

sioner's complete reasoning and the "entire record" to determine whether the "drug classification was arbitrary or capricious" (313a). The District Court was instructed to take only such additional affidavits or testimony as it deemed necessary. There was no ruling that additional affidavits or other testimony were required if scrutiny of the record sufficed.

Judge Friendly's Decision in *National Nutritional Foods Ass'n* v. *FDA*

The genesis of the remand to the District Court and this appeal is the decision written by Judge Friendly in *NNFA* v. *FDA* (sometimes referred to hereafter as Judge Friendly's "decision"). However, in ordering a remand in the instant case because of the intervening decision in *NNFA* v. *FDA*, it was specifically stated that the decision in *NNFA* v. *FDA* did *not* dictate the overturning of the regulations at issue here (313a).* A number of readily apparent differences between the regulations under attack in *NNFA* v. *FDA* and the regulations here were noted (313a-314a).

As Judge Mansfield stated in the decision to remand this case:

> [A]ppellants argue that the [vitamin A and D regulations] must *a fortiori* be invalidated [because of the decision by Judge Friendly in *NNFA* v. *FDA*]. We disagree. We are here dealing with

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* Plaintiffs' statement (App. Brief at 6) that Judge Friendly "noted [his] disagreement" with Judge Frankel's earlier decisions (242a-258a and 282a-302a) finding Vitamins A and D at the regulated levels to be drugs is an obvious misstatement. Judge Friendly found this case distinguishable because of the potentiality for harm from ingestion of vitamins A and D and, if anything, the reference is approving.

> regulations which (1) differ in material respects from § 125.1(h), (2) were promulgated under a different statute, § 701(a), and (3) are subject to a less stringent standard of review . . . . Furthermore, there are several differences between the proceeding before the *NNFA* v. *FDA* court and that here. As to Vitamin A there is a difference between the upper level encountered in *NNFA* v. *FDA* (more than 8,000 IU) and that before us (more than 10,000 IU). Moreover, the present regulations, unlike § 125.1(h), specifically provide that one higher dosage form mentioned as being vended for nutritional purposes in *NNFA* v. *FDA*, *i.e.*, vitamin D up to 1,000 IU per dosage, may be used under medical supervision to meet nutritional requirements provided it's so labelled. Unlike § 125.1(h) which declared on the basis of general reasoning that a broad range of vitamins and minerals are "drugs" when vended in dosages exceeding their RDA's, the regulations here are directed specifically at two vitamins, A and D. This suggests that the Commissioner may be engaged in a more detailed and specific consideration of these vitamins than was apparent in the § 125.1(h) proceeding . . . .
>
> Since the foregoing differences may prove to be significant, invalidation of the regulations here under attack is not automatically mandated by our decision in *NNFA* v. *FDA*. (313a-314a)

Although the application of Judge Friendly's decision to this case and this Court's suggested distinctions between the two cases will be discussed in Point II, *infra*, it is appropriate to describe at the outset the regulations which were before the court in *NNFA* v. *FDA* and to clarify the relationship between those regulations and the Vitamin

A and D regulations at issue here. This discussion is necessitated by plaintiffs' repeated and erroneous assertion that the FDA promulgated the Vitamin A and D regulations on the same rationale and record as the general vitamin regulation reviewed in *NNFA* v. *FDA*. *See, e.g.*, Appellants' Brief at 4-5.

Judge Friendly's comments on the drug definition section of the Act were made in the context of an attack on 21 C.F.R. § 125.1(h), a part of a series of comprehensive regulations involving labeling and composition of all vitamins and minerals, promulgated after extensive hearings and subject to review under a substantial evidence standard. In particular, Section 125.1(h) made any product containing more than the upper limits of the U. S. Government Recommended Daily Allowance ("U. S. RDA's"), including breakfast cereals, milk, etc., a drug. In contrast, the Vitamin A and D regulations apply only to these two vitamins and only when they are produced in medicinal form, such as capsules and tablets.

Acceptance of the FDA's regulation 125.1(h) presented a number of difficulties, which are not present here. The drug definition proffered by the FDA contradicted its own regulation (which treated certain vitamins as foods) and the regulation itself was contradicted by the record (which contained evidence of nontherapeutic usages at the regulated levels). *See also* discussion, *infra*, at 29-30.

Plaintiffs' ground their suggestion that the Vitamin A and D regulations and the regulation involved in *NNFA* v. *FDA* are linked in origin and philosophy on one quotation from the preamble to the Vitamin A and D regulations—a quotation which plaintiffs persist in truncating (Appellants' Brief at 5). In full the quotation reads:

> The question regarding whether a vitamin is a food or drug generated considerable discussion. The tentative and final orders promulgating §§ 80.1, 125.1, and 125.3 (21 CFR 80.1, 125.1 and 125.3), published in the January 19, 1973 Federal Register (38 F.R. 2143, 2152) and elsewhere in this issue of the Federal Register discuss this matter in detail. The Commissioner concludes, on the basis of all the available evidence, that vitamins between the upper and lower limits as specified in § 80.1 are adequate for all known nutritional needs for normal individuals and that nutrients at these levels are dietary supplements which are foods for special dietary use. No evidence was submitted in the comments to establish a food or nutritional use of vitamin A or vitamin D at higher levels, except for a limited number of persons with poor vitamin D absorption who need up to 1000 IU of this vitamin for nutritional purposes under medical supervision. With that one exception, which is recognized in the revised regulation, intake of vitamins at levels exceeding the upper limits as specified in § 80.1 are therefore appropriate only for therapeutic purposes and thus are properly classed as drugs. (38 Fed. Reg. 20723) (32a, 394a).

Even from the quotation alone, it is apparent that the mention of the other vitamin regulations was for informational purposes and as a shorthand reference to the numerical listings in § 80.1, which is reproduced in *NNFA* v. *FDA*. (504 F.2d at 769). There is no reference in the preamble to the vitamin A and D regulations to the hearings on the general vitamin regulations as plaintiffs acknowledge (Brief at 4); indeed, in the portion of the quotation omitted by plaintiffs reference is to the record of the Vitamin A and D regulations.

The contemporaneous Federal Register publications indisputably establish that the Commissioner's central concern was the potentiality for harm from high potency preparations of vitamins A and D and that the Commissioner did not declare these vitamins to be drugs on the impermissible basis discussed by Judge Friendly, *i.e.*, simply because of the absence of a nutritional need.* The regulation itself states: "*In view of the toxicity of excessive consumption of vitamin A, the Food and Drug administration finds that,* in order to protect the public health, oral *preparations containing vitamin A in excess of 10,000 IU* per dosage unit or recommended daily intake *are drugs* subject to section 503(b)(1) of the Federal Food, Drug and Cosmetic Act and shall be restricted to prescription sale." (emphasis added). The same language, adjusted for the appropriate dosage, appears in the regulation for vitamin D. In addition, there are repeated references throughout the Federal Register publications to the Commissioner's concern about the toxicity of vitamins A and D, and there can be no dispute that there is ample record support for this concern. Scientifically, the toxic properties of vitamins A and D derive in part from the fact that they are fat soluble vitamins (in contrast to water soluble ones) and therefore accumulate in fatty tissue. (35a).

In short, the Commissioner's concern about vitamins A and D was not simply that they were nutritionally useless. His concern about their potentiality for harm and toxicity prompted the Commissioner to act separately to regulate high dosage preparations of vitamins A and D

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* The Commissioner's affidavit confirmed this focus: "In promulgating these regulations, concern over the public harm that could be done by these high potency therapeutic preparations weighed more heavily upon my mind than any other single factor." (385a)

as prescription drugs. The other vitamins and minerals for which U. S. RDA's were established by the general vitamin regulations were not so regulated. The coincidence of promulgation date and one reference to the general vitamin regulations does not transform the separate vitamin A and D regulatory proceeding into an offshoot of the general vitamin regulations.

The Recent Legislation on Vitamins and Minerals

Plaintiffs take the position that recently enacted Section 411 of the Act, 21 U.S.C. § 350, undermines the basis for the vitamin A and D regulations. As demonstrated above and to be more fully discussed below, part of plaintiffs' argument rests on the erroneous premise that the vitamin A and D regulations were promulgated solely because there was no nutritional use for them at the regulated levels.

In applicable part, the new statute provides:

> (B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful . . . . (21 U.S.C. § 350(a)(1)(B)).

In legislating that the Secretary of Health, Education and Welfare could not classify a vitamin as a drug "solely" because it lacks nutritional usefulness, the Congress echoed this Court's decision in *NNFA* v. *FDA*, *supra* at 788-89.

The true significance of the new legislation is that Congress specifically endorsed the approach utilized by the defendants in this case, applying the prescription pro-

visions of the Act to vitamins A and D because they are not safe for unsupervised use:

> The Secretary also has the authority to regulate the composition and potency of a product subject to the provisions of the conference substitute on the basis of safety. If a high potency preparation of a vitamin or mineral is a drug as defined by section 201 (g) of the Act and the Secretary determines that within the meaning of section 503 (b) of the Act, it is not safe for use except under the supervision of a physician, such a high potency preparation is subject to regulation as a prescription drug under the Act." (622a)

Plaintiffs' argument to the contrary at p. 18 of their brief is simply wrong.

The new legislation (614a-616a) was intended to curtail FDA's authority to restrict maximum potency and combination of ingredients in *safe* dietary supplements of vitamins and minerals; it was explicitly *not* intended to curtail FDA's authority to impose restrictions on vitamin/mineral preparations for reasons of safety.

The vitamin and mineral amendments were added by the Senate to the Health Research and Health Services Amendments of 1976 (often described as the "heart and lung bill" before enactment). On December 11, 1975 when the Senate approved the addition of the vitamin and mineral amendments to the heart and lung bill and passed the entire bill as amended, Senator Schweiker introduced the report to accompany the vitamin/mineral legislation and described the purpose and scope of the legislation:

> This amendment does not restrict the FDA from controlling any vitamin or mineral preparation which is shown to be toxic. Chapter V of the

> Food, Drug, and Cosmetic Act, which states that a product is a drug if it is toxic, habit forming, or must be administered by a physician, is not changed by this amendment. It simply adds a new section to Chapter IV, the food section of the Act. *The FDA already restricts the potency of vitamins A and D, because they have been shown to be toxic in high doses. This amendment does not rescind this authority.* (121 Cong. Rec. S21857 (daily ed. Dec. 11, 1975)) (emphasis added).*

Thereafter, a conference committee of the House and Senate agreed to the Senate's addition of the vitamin and mineral provisions to the heart and lung bill, with a few minor revisions not pertinent here. Identical conference reports were filed in the House and Senate.** Both of these reports repeatedly emphasized that FDA retains full authority to limit potencies of vitamins and minerals for reasons of safety (618a-622a).

This feature of the legislation was highlighted in the comment of Congressman Rogers (Chairman of the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce) whose staff was involved with the staffs of Senators Schweiker and Proxmire in evolving the compromise legislation that became law. (121 Cong. Rec. S. 21857 (daily ed. Dec. 11, 1975)). Congressman Rogers' comment is reproduced in

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* The Senate's consideration and passage of the heart and lung bill, including the vitamin and mineral amendment, appears in the Congressional Record-Senate for December 11, 1975, pages S21845-S21870.

** H. Rep. No. 94-1005, 94th Cong. 2d Sess. (April 2, 1976); S. Rep. No. 94-743, 94th Cong. 2d Sess. (April 8, 1976).

part in the margin.* Both Houses of Congress subsequently accepted the conference report and passed the legislation.**

In sum, in passing the new legislation, Congress specifically sanctioned the regulatory procedure followed by the defendants here.***

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* "Title V of the conference substitute is designed to clarify the authority of the Food and Drug Administration regarding safe vitamin and mineral food supplements. The substitute would preserve the right of the individual to continue to freely purchase safe vitamins and minerals in tablets, capsules, small units of liquid measure, and certain other forms, while protecting the public from potentially unsafe and deceptively labeled and advertised products. Under the conference substitute, the FDA would be prohibited from classifying vitamins and minerals as drugs solely on the basis that they exceed the level of potency that the FDA determines is nutritionally rational or useful. The FDA would be restricted from prohibiting safe ingredients and safe potencies of vitamins and minerals if they occur in combinations other than those authorized under FDA regulations.

"The conference substitute would not, however, alter the authority of the FDA under chapters IV and V of the Federal Food, Drug, and Cosmestic Act to regulate these products where there is evidence that they may be toxic, habit forming, carcinogenic, or where they are not generally recognized among qualified experts to be safe under the conditions of their intended use, or where they are otherwise not safe for use except under the supervision of a licensed practitioner.

"The provisions in the conference substitute would not alter the authority of the FDA to regulate these products as drugs under chapter V of the act if they are represented for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." (122 Cong. Rec. H3245 (daily ed. April 12, 1976)).

** 122 Cong. Rec. H3244-H3248 (daily ed. April 12, 1976); 122 Cong. Rec. S5507-S5508 (daily ed. April 12, 1976). The legislation was signed by the President on April 22, 1976. P.L. 94-278; 90 Stat. 410-413.

*** Accordingly, plaintiffs' comment at p. 28 of their brief that "Significantly, the District Court failed to even discuss the applicability of this statute, which was enacted on April 22, 1976" is inappropriate. The comment by plaintiffs is even more inappropriate because although invited to place the statute before the Court (541a), plaintiffs failed to do so and at no time briefed the issue to the District Court.

ARGUMENT

POINT I

The District Court complied with this Court's remand order.

Plaintiff-manufacturers complain about two aspects of the proceedings in the District Court following the order of remand. First, plaintiffs contend that the District Court erred in accepting an affidavit of the Commissioner and then compounded that error by refusing to permit plaintiffs to cross-examine him. Second, plaintiffs contend that they should have been given access to privileged documents from the agency files consisting of deliberative memoranda and prior drafts of the regulations at issue.

A. The proceedings below following the order of remand.

After this Court's decision of February 3, 1975 the defendants submitted an affidavit of Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, sworn to on March 21, 1975 (317a-371a) along with a memorandum of law. After an exchange of memoranda a conference was held before Judge Frankel on September 4, 1975. At that time Judge Frankel indicated that he believed it appropriate that the proceedings on remand await the Supreme Court's determination of the petition for certiorari filed by plaintiffs from this Court's decision of February 3, 1975.* Judge Frankel also directed that the Commissioner submit a revised affidavit which would omit references to certain scientific

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* The petition for certiorari was denied. 94 S.Ct. 44 (1975).

material published after the promulgation of the regulations. Judge Frankel further directed that the Government search its files to determine whether there were any additional record materials therein. Both parties were directed to submit memoranda to the Court noting those portions of the record upon which they intended to rely.

In accordance with the directions of Judge Frankel, the Government submitted a revised affidavit of Commissioner Schmidt, sworn to on February 13, 1976, discussing the Commissioner's reasoning in classifying high potency preparations of vitamins A and D as drugs. (377a-447a). Defendants also submitted a thirty page memorandum discussing the administrative record and conducted an extensive search of the files of the defendants. (Plaintiffs, incidentally, submitted no similar memorandum about the record.) That search yielded a number of documents.* Included in the newly located material were a few communications with the FDA by certain physicians during the time period between the proposal and the promulgation of the regulations. In the Government's view those were the only documents located which arguably should have been included in the record previously filed with the Court. Also located was correspondence predating the proposal of these regulations, correspondence postdating the enactment of these regulations and some medical articles. Although in the Government's view these documents were not properly part of the rec-

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* See the affidavit of Stephen H. McNamara, Associate Chief Counsel for Food of the FDA, describing (1) the formally docketed public record compiled by FDA in the course of the notice and comment rulemaking proceeding; (2) the search made by FDA, pursuant to Judge Frankel's Order, for any additional relevant documents that might exist in agency files; and (3) the nature of the additional documents uncovered in the search (372a-376a).

ord, they were, nevertheless, turned over to the Court and plaintiffs on a voluntary basis and without prejudice to the defendants' position that they were not properly part of the record (554a, 569a). The only material withheld was that material considered by the defendants to be privileged as intra-agency deliberative communications. The defendants' position was upheld by the Court below (569a-570a) after the Court examined the withheld records *in camera.** We turn now to the arguments raised by plaintiffs concerning the District Court's conduct on remand.

B. Acceptance of Commissioner Schmidt's affidavit without cross-examination was proper.

This Court's remand direction was a flexible one:

> Accordingly, we remand the case to the district court with directions to conduct an *Overton*-type hearing (including such affidavits or testimony as to the Commissioner's reasoning as the court deems necessary) for the purpose of determining whether, upon the entire administrative record before the Commissioner, which the court should scrutinize, Silva v. Lynn, 482 F.2d 1282 (1st Cir. 1973), the Commissioner acted rationally in classifying the higher Vitamin A and D dosage levels as a "drug" within the meaning of § 201(g) of the Act, 21 U.S.C. § 321(g). (314a).

Likewise, the Supreme Court's decision in *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402

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* The documents submitted to the District Court *in camera* will be submitted to this Court under seal on the day of argument or at such earlier time as the Court may direct.

(1971), ("*Overton Park*") gave a district court discretion to determine the best way to proceed. At least three procedures were suggested: (1) remand to the agency, 401 U.S. at 419, n. 33; (2) preparation of formal findings by the agency, 401 U.S. at 420 and (3) testimony from the decisionmaker, *Id.* Additionally, the learning of *Overton* must be evaluated in terms of the Supreme Court's later decision in *Camp* v. *Pitts*, 411 U.S. 138 (1973). In *Overton* there was no contemporaneous administrative record. Thus, the Supreme Court proffered a number of alternatives by which a record could be created. However, in *Camp* v. *Pitts*, the Supreme Court made it clear that when there is a contemporaneous agency record which is determined to be inadequate, the proper remedy was remand to the agency for further consideration, 411 U.S. at 142-43.*

Apart from the specific sanction given by this Court to the affidavit procedure adopted by Judge Frankel, an examination of relevant cases supports the approach utilized. As noted above, *Overton Park* suggested such a procedure. More recently, the Supreme Court, in the case of *Dunlop* v. *Bachowski*, 421 U.S. 560 (1975), afforded the Secretary of Labor the "opportunity to supplement his statement", *Id.* at 574, while specifically rejecting cross-examination of the Secretary as an appropriate procedure, *Id.* at 572-74.

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* The proceeding on remand in *Overton* is not, as plaintiffs suggest, particularly instructive. First, even on remand the Secretary failed to submit formal findings and refused to have his affidavit considered as findings. 385 F. Supp. 873 at 877-78. Thus, the agency did not, as here, supplement the record in the district court. Second, *Overton Park* is not a case involving informal agency rule-making on a publicly available administrative record.

Another approach, and perhaps one more frequently employed, is a remand to the agency, *Camp* v. *Pitts*, 411 U.S. 138, 142-43 (1973); *Local 814, Int. Bro. of Teamsters* v. *N.L.R.B.*, 512 F.2d 564 (D.C. Cir. 1975); and Wright, "The Courts and the Rule Making Process: The Limits of Judicial Review", 59 Corn. L. Rev. 375, 396 (1974) (hereinafter referred to as "Wright").* However, whether the procedure of remand to the agency or the supplementation of the record in the District Court is utilized, the result is essentially the same. The agency is given an opportunity to more adequately explain its actions and those actions should once again be examined under the arbitrary and capricious standard of review.**

Plaintiffs' suggestion, which Judge Frankel specifically rejected (568a), that there is something so out of the ordinary or suspicious here that there should be a departure from the usual procedure of review of the agency's record without cross-examination, is unfounded. It should be remembered that the necessity for the remand by this Court arose from a decision of the Second Circuit subsequent to the agency's action and not because the agency's initial efforts were at the time inadequate. Second, the subject of the remand to this Court is one requesting clarification and does not involve a reversal of the agency's position. (Compare Pedersen "Formal Records and Informal Rule Making", 85 Yale L. J. 38,

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* *See also*, Friendly, "Some Kind of Hearing", 123 U. Pa. L. Rev. 1267, 1313-14 (1975).

** It is noted, however, that the Supreme Court in *Overton Park* suggested that supplementation of the record would "to some extent, be a 'post-hoc rationalization' and this must be viewed critically." 401 U.S. at 420. More generally though, the fact that the agency knows the issue which has been remanded does not alter the standard of judicial review. Wright, 396, n. 93.

78 n. 147 (1975)) (hereinafter referred to as "Pedersen"). Again in faulting the Commissioner's affidavit, plaintiffs persist in the specious argument that the vitamin A and D regulations were based on the record and reasoning of the general vitamin regulations. Most of the so-called deficiencies in the Commissioner's affidavit stem from this false assumption. (See discussion *supra* at 7-10). Other queries raised by plaintiffs are more properly related to the issue of prescription status for these levels of Vitamins A and D, an issue already resolved by this Court in favor of the defendants (315a). Additionally, although the Commissioner's affidavit was the new item of evidence before the District Court, the lower court's decision was to be based on a careful review of the entire record in light of an intervening decision. There was, as will be shown below, a wealth of supportive material in that record. See Point II, B, *infra*. The virtually exclusive focus by plaintiffs on the affidavit of the Commissioner is distorting.

Thus, given the facts of this case, there is no reason to confer upon plaintiffs greater rights (to wit, the right of cross-examination of the Commissioner) at this stage of the review process than they would normally be entitled to. If the matter were remanded to the agency, the agency's action and its review would occur without hearing or cross-examination (308a-309a). Even in the case of supplementation in the District Court, the most that the Supreme Court has suggested is that the supplementary submission be examined more closely. *Overton Park*, 401 U.S. at 420. Allowing cross-examination of the Commissioner would be, it is submitted, an unwarranted violation of the rule of *United States* v. *Morgan*, 313 U.S. 409 (1941), against examination of the thought process of

the decision maker.* *See also, Dunlop* v. *Bachowski, supra.* Any question that the principle of *Morgan* might not be applicable to review of agency rulemaking was eliminated by another decision by Judge Friendly in *National Nutritional Foods Association* v. *FDA*, 491 F.2d 1141, 1145 (2d Cir. 1974). There are no facts here which would indicate bad faith or improper behavior on the part of the FDA such as to justify a departure from *Morgan.* Clearly the issue here arose from an intervening decision of the Second Circuit and, at most, the agency is being asked to explain further its decision on the issue of drug classification. Moreover, there is ample support in the record, even without Commissioner Schmidt's affidavit, to satisfy the formulation by the Second Circuit of the drug classification issue. See Point II, C, *infra.* As Judge Wright has noted, "a rulemaker can surely demonstrate his seriousness and good faith without allowing interested parties to cross-examine him or quarrel orally before him". (Wright, 394).

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* Additionally, as this Court observed in rejecting plaintiffs' argument that they were entitled to *de novo* review in the District Court:

> Since the decision did not turn on precise factual issues or on the credibility of witnesses but represented a judgment based upon consideration of relevant medical and scientific data, we doubt that a trial-type adversary hearing would have shed any further light on the question of whether restriction of the sale of higher dosage levels of Vitamins A and D to prescription sale would be in the public interest. The question was one to be resolved on the basis of a general appraisal of the risk of toxicity. (311a).

We submit that that observation is equally apt in connection with whether vitamins may be classified as drugs.

C. Plaintiffs have received all record material to which they are even arguably entitled.

(1) The Record

In the District Court, the defendants maintained that the "record" upon which review of informal agency rule-making is to be based is limited to the following documents: (1) the notice of proposed rulemaking published by the FDA, including the terms of the proposed regulation, a preamble explaining the Agency's reasons for issuing the proposal, and all documents incorporated by reference therein; (2) the comments and supporting documents filed by interested persons (including plaintiffs) in response to the proposal, which were available for public scrutiny and cross-comment by any interested person; and (3) the Agency's Federal Register publication of the final regulation, including a preamble analyzing the issues raised in the comments. (373a-374a).*

We submit that the commentators and the cases treating this issue are in accord that it is this administrative record, compiled by the FDA in the course of the notice-and-comment rule-making proceeding and submitted at the outset, that is the proper record for purposes of judicial review. *Rodway* v. *USDA*, 514 F.2d 809, 817 (D.C. Cir. 1975) ("The whole record in an informal rule-making case is comprised of comments received, hearings held, if any, and the basis and purpose statement.");

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* At the District Court's urging (527a-528a) and in the "spirit of accommodation" (569a) defendants turned over all additional documents arguably related to the rule-making proceeding other than a few withheld as privileged.

We do not disagree that correspondence between third parties and the agency during the period between proposal and promulgation should be made part of the record. However, since comments are supposed to be addressed to the Hearing Clerk, correspondence otherwise addressed may not be automatically included in the record due to the clerical difficulties imposed.

Automotive Parts & Accessories Ass'n v. *Boyd*, 407 F.2d 330, 336 (D.C. Cir., 1968) (". . . there *is* a record compiled in a Section 4 proceeding, and available for filing in court. It consists of the submissions made in response to the invitations issued for written comments." [Emphasis in original]); *National Petroleum Refiners Ass'n* v. *FTC*, 392 F. Supp. 1052 (D.D.C. 1974) (in action for review of notice-and-comment rule-making, protective order entered to prevent discovery of documents in FTC files that were not a part of the administrative record compiled by the FTC pursuant to Section 4 procedures). *See also Boating Industry Ass'n* v. *Boyd*, 409 F.2d 408, 410-412 (7th Cir. 1969); Pedersen at 64-65 and Verkuil, "Judicial Review of Informal Rulemaking", 60 Va. L. Rev. 185, 248 (1974).

The definition of the record as suggested is sound for several other reasons. First, there is a logical relationship between the requisites for informal agency action as set forth in Section 4 of the Administrative Procedure Act, 5 U.S.C. § 553, and the record upon which such action should be reviewed. It would be illogical to conclude that the record for review should be different from or exceed the record required by the Administrative Procedure Act for such agency action. In fact, this Court in the prior appeal of this case, related the record requirement to the underlying nature of the rule-making proceeding. (311a-312a). Under Section 4 of the Administrative Procedure Act the FDA was required to publish notice in the Federal Register, give interested persons an opportunity for comment and then "[a]fter consideration of the relevant matter presented . . . incorporate in the rules adopted a concise general statement of their basis and purpose."*

* Indeed, this Court has ruled that FDA complied scrupulously" with these requirements in the vitamins A and D proceedings (311a). See also 260a-261a.

Second, definition of the record for purposes of judicial review to conform to the record created by the agency in the course of its Section 4 proceeding is also likely to improve the quality of the agency's preambles (Pedersen at 73). As Judge Wright has noted, "If accorded a properly expansive reading, section 553 provides a fully adequate scope for judicial review of rule-making." (Wright at 380 and see discussion at 394-395.)

Lastly, the approach of the Government is supported by other basic principles of review of administrative action. Permitting a challenging plaintiff to rummage through the agency's files for intra-agency deliberative memoranda and early working drafts of the regulation in the absence of any indication of wrongdoing or lack of good faith is an invasion of the traditional governmental privilege for intra-agency deliberative memoranda akin to the invasion of the mental processes of the decision maker. *United States* v. *Morgan*, 313 U.S. 409 (1941) and *see* Pedersen at 72 and 84. Furthermore, there is no indication that an act of rule-making was intended to be a general repeal of the privilege against disclosure of intra-agency deliberations which has recently received legislative recognition in the Freedom of Information Act, 5 U.S.C. § 552(b)(5). (Pedersen, 84).

In addition, the citations on this issue in appellant's brief are inapposite in that they do not involve review of informal agency rule-making or are otherwise distinguishable. First, plaintiffs' citation to *Silva* v. *Lynn*, 482 F.2d 1282 (1st Cir. 1973), wholly misconstrues the relevance of that decision to this case. We believe that when this Court remanded the "drug issue" to the District Court with a citation to *Silva*, it was *not* ordering the District Court to deviate from traditional practice and assemble some greater record, but rather it was directing the District Court to satisfy itself of the presence of the "whole record", 5 U.S.C. § 706, and then to "scrutinize" that record to determine whether, in light of the record, "the Commissioner acted rationally". (314a).

In *GTE Sylvania Inc.* v. *Consumer Products Safety Commission*, 404 F. Supp. 352 (D. Del. 1975), plaintiffs were seeking to prevent the Commission from releasing to the public certain information relating to television safety. Rule-making was not involved, 404 F. Supp. at 367, n. 65, and it does not appear that there was a definitive administrative record compiled pursuant to 5 U.S.C. § 553 at the time of the administrative action, such as FDA has provided in this case. The situation in *Schicks* v. *Romney*, 474 F.2d 309 (2d Cir. 1973) was similar.

In *Natural Resources Defense Council, Inc.* v. *Train*, 519 F.2d 287 (D.C. Cir., 1975), EPA offered the district court an "administrative record", 519 F.2d at 289, which does not appear to have been defined by the agency during the rulemaking proceeding. Plaintiffs then filed an affidavit which made a "substantial showing . . . that the Administrator had not filed the entire administrative record"; in his response the Administrator did *not* claim that he had filed the entire record. 519 F.2d at 289, 291. Furthermore, EPA withheld a "Briefing Book" sought by plaintiffs until the case was before the court of appeals, and then admitted that the book was properly a part of the record although it had been denied to the district court. 519 F.2d at 291, 292. Under such circumstances, the decision of the appellate court that plaintiffs had shown themselves to be "entitled to an opportunity to determine, by limited discovery, whether any other documents which are properly part of the administrative record have been withheld," 519 F.2d at 292, is certainly understandable, but has little relevance here.*

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* There is another reason that plaintiffs' repeated reliance on cases involving environmental impact statements is wholly inappropriate. Required agency action under the National Environmental Policy Act, 42 U.S.C. § 4321 *et seq.* is subject to a different standard of review than agency action within the meaning of the APA. *National Helium Corporation* v. *Morton*, 486 F.2d 995-1001 (10th Cir. 1973), *cert. denied*, 416 U.S. 993 (1974).

In *Smith* v. *FTC*, 403 F. Supp. 1000 (D. Del., 1975), the Federal Trade Commission appears to have simply "adopted" by "resolution" published in the Federal Register the line of business program involved, 403 F. Supp. at 1003, n.1. Apparently, the FTC admitted non-compliance with APA rule-making requirements. 403 F. Supp. at 1006, n.18. *See also* 403 F. Supp. at 1008, n.22. Furthermore, unlike the FTC in *Smith*, 403 F. Supp. at 1008, the FDA here does not argue that it has a right to rely, in supporting its regulation only upon selected portions of the record or upon evidence not included in the record. And unlike the case at bar, the court in *Smith* found that " 'contemporaneous explanations' of the Commission's actions . . . are lacking", 403 F. Supp. at 1012, and thus a record had to be created initially at the time of judicial review.

One other observation seems appropriate. Plaintiffs make numerous references to cases involving agencies which attempted to rely on extra-record material in efforts to prevail. In this case, the defendants, other than as ordered by this Court, did not seek to introduce extra-record material. Here the FDA has expressed its willingness to be bound by the record created at the time the regulation was promulgated (374a).

(2) The assertion of the deliberative privilege.

In addition to their claim that they were entitled to receive privileged, intra-agency deliberative documents, plaintiffs, relying on *United States* v. *Reynolds*, 345 U.S. 1 (1952), also complain that the privilege was not properly asserted in that it was not claimed by the head of the defendant agency. *Reynolds* involved a claim by the Government of its military secrets privilege. *Id.* at 7. The Supreme Court held that when an executive agency claims a privilege against production on the ground that

the requested documents are military or state secrets, the claim must be asserted by the head of the agency after personal review of the relevant documents. *Id.* at 7-8.

Here the defendants have not asserted the military or state secrets privilege, but rather their deliberative privilege. Since some courts have treated these and other governmental privileges, although disparate, under the single rubric of "executive privilege", this has lead some lower courts, without consideration or reason, to require the Government to follow the same procedures when claiming its deliberative privilege as it must when it claims its state secrets privilege. Analysis of the issue makes it clear that such a requirement is illogical and without foundation.

The determination that a document contains military or state secrets, the revelation of which will endanger national security, is inherently a high level policy decision. Moreover, unless the claimant can make a very substantial preliminary showing that the documents have been improperly classified, courts are reluctant to examine the documents and substitute their judgment for that of the agency. Furthermore, no demonstration of the claimant's need may overcome a proper assertion of this privilege. *See, United States* v. *Reynolds, supra* at 8-11; *Bennett* v. *The United States Dept. of Defense*, 419 F. Supp. 663 (S.D.N.Y. 1976). Consequently, when the state secrets privilege is asserted by the Government, a court must rely very heavily on the judgment of the responsible executive officer; it must be clear that such judgment was properly exercised. *Kinoy* v. *Mitchell*, 67 F.R.D. 1, 9 (S.D.N.Y. 1975). Thus, it is reasonable to require that a claim of state secrets privilege be made by the head of the executive agency, after personal consideration.

On the other hand, the Government's deliberative privilege does not involve national security or military policy determinations which must be individually analysed, but rather, is intended to protect the Government's deliberative or decision making processes, *e.g.*, *N.L.R.B.* v. *Sears, Roebuck and Co.*, 421 U.S. 132, 150 (1975).

Whether or not a given document is part of this process is clear from its face and *in camera* inspection of such deliberative documents is permissible and commonplace. *E.g.*, *E.P.A.* v. *Mink*, 410 U.S. 73, 93 (1972) ("*Mink*"). Thus, the unique qualities of the state secrets privilege, which require surrounding its assertion with several procedural safeguards are absent when the deliberative privilege is asserted. Consequently, it is unnecessary to engraft these procedural safeguards onto claims of the deliberative privilege.

The Supreme Court's recent decision in *Mink* set forth the procedure to be followed by the Government when claiming Exemption b(5) under the Freedom of Information Act ("FOIA")* after it was made clear that the b(5) exemption was simply a codification of the Government's pre-existing common-law, deliberative privilege. *Mink*, *supra* at 86. The Court ruled that the agency, as distinguished from its head, could demonstrate that the withheld matter was part of its deliberative process by a combination of affidavit and *in camera* inspection of a representative sample of the withheld documents. *Mink*, *supra* at 93.** Here, of course, FDA submitted an

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* 5 U.S.C. § 552(b)(5) exempts from disclosure under the FOIA: "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency."

** Perhaps the best indication of the Supreme Court's intent in this portion of the *Mink* decision may be gleaned from its

[Footnote continued on following page]

affidavit by its Associate Chief Counsel for Food asserting the privilege (375a) and the District Court examined all the documents, sustaining FDA's claim of privilege without exception.

Clearly, it would be irrational to require the Government to adhere to one set of procedures for claiming its deliberative privilege in a FOIA suit, but to require adherence to a different set of procedures for claiming this same privilege in other civil actions. Cases adopting a unified approach include *United States* v. *J. B. Williams*, 402 F. Supp. 796, 797-98 (S.D.N.Y. 1975); *Wu* v. *Keeney*, 384 F. Supp. 1161, 1165-66 (D.C.D.C. 1974).

In sum, the procedure followed by the District Court conformed to this Court's remand order and was entirely proper.

POINT II

Vitamins A and D at the regulated levels have properly been classified as drugs.

A. Vitamins A and D are drugs because the regulated levels exceed the nutritional levels in the United States Pharmacopeia and the National Formulary.

The discussion in Point II is mainly in the context of subsection (B) of the Act's drug definition and in the context of this Court's earlier decision on appeal. How-

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Proposed Rule of Evidence 509 which was promulgated two weeks after the argument in *Mink* on November 20, 1972, 56 F.R.D. 183 (1973). Proposed Rule 509, 56 F.R.D. at 251-52, provided that while the state secrets privilege could only be claimed by the chief officer of the agency or department the "official information" privilege "may be asserted by any attorney for the government."

ever, we do not, despite its rejection as post-hoc rationalization by the Court below, retreat from our position that the Commissioner can properly rely on subsection (A) of the drug definition as a separate basis for classifying these levels of vitamins A and D as drugs.

Subsection (A) of Section 201(g)(1), 21 U.S.C. § 321(g)(1), provides:

> The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them. . . .

Vitamins A and D are recognized in the United States Pharmacopeia ("USP"), and The National Formulary ("NF"). (See the affidavit of Commissioner Schmidt (¶ 6) (382a-384a).

In the *NNFA* v. *FDA*, Judge Friendly rejected the FDA's reliance on subsection (A) in the challenge to the general vitamin regulations on the grounds that (a) it constituted appellate counsel's post-hoc rationalization; and (b) acceptance of the argument "would prove too much, for it would lead to the conclusion that all vitamin and mineral preparations even within the limits are drugs—a position which would run counter to the regulations" [which only classified vitamins and minerals above the U.S. RDA's as drugs]. 504 F.2d at 789.

The situation here is distinguishable from the one presented to Judge Friendly for several reasons. First, the reliance on subsection (A) is not based solely on argument initiated by counsel in a brief, but is articulated by the Commissioner of Food and Drugs, the agency head, in an affidavit. Second, while vitamins A and D are recognized in the USP and in the NF for both food and drug

purposes, the regulated levels of vitamins A and D *exceed* the recognized food usages for both vitamins. If subsection (A) of the drug definition is read, and we submit that it is reasonable to do so, as "recognized in the USP and the NF for non-nutritional, i.e. therapeutic purposes", then consistent with the plain language of § 201 (g) (1) (A), vitamins A and D should be classified at the regulated levels as drugs. This reading of subsection (A) does not result in the problem perceived by Judge Friendly, to wit, that reliance on inclusion in the USP and the NF "would prove too much." First, relying on this analysis of subsection (A), all quantities of vitamins A and D are not classified as drugs, only those higher levels recognized for therapeutic purposes. Second, acceptance of the Commissioner's position that these levels of vitamins A and D are drugs does not result in the automatic acceptance of the challenged regulatory action. A separate determination that vitamins A and D should be regulated as prescription drugs is still required to sustain the regulations. Section 503, 21 U.S.C. § 353(b). This is in contrast to the situation before Judge Friendly where acceptance of the FDA's argument would have meant blanket classification of all the vitamins and minerals as drugs, in contradiction to its own regulations, and would have resulted in the compulsory application to all vitamins and minerals of all the provisions of the Act relating to drugs. See Affidavit of Commissioner Schmidt (382a-384a).

With respect to Judge Frankel's comment that this analysis of subsection (A), which he acknowledged had "weight", "would appear to suffer the fatal disorder of post-hoc rationalization", we make the following observations: prior to Judge Friendly's decision there was no question that inclusion in the USP or the NF was sufficient to make an item a drug. *See e.g., United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784,

790 n. 5 (1969); *United States* v. *Dianovin Pharmaceuticals, Inc.*, 475 F.2d 100, 103 (1st Cir.), *cert. denied*, 414 U.S. 830 (1973); *AMP Inc.* v. *Gardner*, 389 F.2d 825, 827, 830 (2d Cir. 1968); *United States* v. *Articles of Drugs*, 263 F. Supp. 212, 215 (D. Nebr. 1967). Accordingly, by operation of law, vitamins A and D were drugs. Judge Friendly's decision was the first indication that the statute did not bear its plain meaning. Thus, it is virtually impossible for any comment by the Commissioner after Judge Friendly's decision not to have a certain aura of post-hoc rationalization. We submit that it is extending the prohibitions of the doctrine of post-hoc rationalization, which is a bar to the arguments of counsel and not to clarifications by the agency head, too far to use it to negate agency action which predated a court decision narrowing the agency's authority when the action in issue is within the scope of the agency's authority as narrowed.

B. The Objective Evidence Standard: "Something more than demonstrated uselessness as a food for most people."

We turn now to a discussion of subsection (B) of the drug definition as that subsection has been interpreted by this Court. In *NNFA* v. *FDA*, Judge Friendly rejected the blanket classification as drugs of all vitamins and minerals in excess of the upper limits of the U. S. RDA's simply because there is "no known food or nutrition use of nutrients at such high levels". 504 F.2d 789. Similarly, as discussed above, Congress has recently amended the Act to prevent the Secretary from classifying "any natural or synthetic vitamin or mineral (or combination thereof) as a drug *solely* because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful; . . ." 21 U.S.C. § 350(a)(1)(B). (Emphasis added.)

Both Judge Friendly in *NNFA* v. *FDA* and Judge Mansfield in the earlier decision in this case recognized that an objective standard must be utilized to determine whether particular items are drugs within the meaning of Section 201(g) of the Act, 21 U.S.C. § 321(g), to wit, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." Judge Friendly, while acknowledging seller's intent as the "crucial element", made it explicit that the seller's "intent" was to be determined on an objective basis.

> While we agree that a factfinder should be free to pierce all of a manufacturer's subjective claims of intent and even his misleadingly "nutritional" labels to find actual therapeutic intent on the basis of objective evidence in a proper case, such objective evidence would need to consist of something more than demonstrated uselessness as a food for most people. (504 F.2d at 789).

Similarly, Judge Mansfield discussed the objective standard to be applied.

> It is conceivable, for instance, that the Commissioner had before him information demonstrating that the higher dosage forms were used almost exclusively for therapeutic purposes. *Measuring intent on an objective basis, as it must be,* he may have concluded that in view of the extremely small percentage used for nutritional purposes Vitamins A and D at higher dosage levels were intended for use in the "cure, mitigation, prevention or treatment of disease." In that case his action could hardly be arbitrary or capricious and the regulations could, consistently with NNFA v. FDA, be upheld. (314) (emphasis added).

Despite the clear direction of this Court that the standard to be applied is an objective one, plaintiffs repeatedly urge that a drug classification must be based on the subjective intent of the manufacturer and the consumer of the product. Plaintiffs' position cannot withstand even cursory analysis, as two illustrations in Commissioner Schmidt's affidavit make apparent:

> Similarly, if I were promulgating today a regulation concerning the labeling of an oral penicillin product, or a polio vaccine to be dispensed on a sugar cube, I would not seriously pause for long over some objection that such products were 'foods' (379a).

The objective evidence of therapeutic intent spoken of is not and cannot be dependent upon the seller's or consumer's intent.*

Moreover, Judge Mansfield enumerated a number of factors which potentially distinguished these regulations from the ones struck down by Judge Friendly. (313a-314a and see discussion *supra* at 6).

Lastly, in a determination of whether the FDA has arbitrarily and capriciously classified high dosage preparations of Vitamins A and D as drugs, the general principle, as noted by Judge Mansfield, is that the definitional sections of the Act are to be construed liberally to secure the protection of the public's health and that the agency's determinations on classification are to be given considerable weight. (312a-313a). The Supreme

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* Of course, a manufacturer's therapeutic claim for an item can result in that product's regulation as a drug. *See e.g. United States* v. *Hohensee*, 243 F.2d 367 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957); *United States* v. *24 Bottles of "Sterling Vinegar and Honey, etc."*, 338 F.2d 157 (2d Cir. 1964); *United States* v. *Millpax, Inc.*, 313 F.2d 152, 153-54 (7th Cir. 1963).

Court in *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1969)* made it plain that the definition of a drug is not limited to a strict medical definition; that the Act's scope is intended to be as broad as its literal language, and that in determining within which category an article lies, a proper consideration is the type of regulation and public protection which would result from drug classification.** This Court has indicated that it may even be appropriate to work backwards from the regulatory effect to the definitional determination. *AMP Inc.* v. *Gardner*, 389 F.2d 825, 829 (2d Cir.), *cert. denied*, 393 U.S. 825 (1968).

C. The Objective evidence of record supports the classification of these high dosages of vitamins A and D as drugs.

In this section, the defendants will examine the record compiled by FDA during the promulgation of the vitamin A and D regulations and Commissioner Schmidt's affidavit in light of the decisions of this Court on the classification of vitamins as drugs. It is submitted that the contemporaneous administrative record provides ample support for the drug classification and, to the extent that supplementation is necessary, that Commissioner Schmidt's affidavit makes the agency's experience part of the record. (312a, fn. 11). In promulgating the vitamin A and D regulations, the Commissioner relied in part upon more than one hundred scientific articles which document the

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* *Bacto-Unidisk* involved an antibiotic sensitivity disc that did not come in contact with the patient's body but, nevertheless, was held to be a drug.

** See paragraph 9 of Commissioner Schmidt's affidavit which details some of the regulatory benefits which would redound to the public from the classification of these levels of Vitamins A and D as drugs. (387a-388a).

therapeutic use and potential for toxic effect of Vitamins A and D. (See 37 Fed. Reg. 26618, 330a). Appellants have filed a bound compilation of these articles, entitled Exhibits, with the Court; citations to this compilation begin with "E".*

(1) Normal healthy persons have no nutritional need for more than the regulated levels of vitamins A and D.

The appropriate point of departure for this discussion is the fact that the contemporaneous administrative record amply supports the Commissioner's conclusion that the record evidence did not "establish a food or nutritional use of vitamin A or vitamin D" (32a) above the regulated levels.** Judge Friendly did not suggest that uselessness as a food was not a proper consideration, but only that it could not be the *sole* basis for drug classifica-

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* There are two articles on Vitamin A which summarize well the clinical evidence and the concern about the overuse of Vitamin A. We, therefore, refer the Court to the following articles in their entirety: Oliver, "Chronic Vitamin A Intoxication", *A.M.A. J. Diseases of Children* (1958), at E258-269; American Academy of Pediatrics, "The Use and Abuse of Vitamin A", *Pediatrics* (1971), at E365-E366. Similarly, with respect to Vitamin D, two medical articles in the administrative record provide well-documented overall treatment of the need for Vitamin D and the dangers of its overuse. We refer the Court to Taussig, "Possible Injury to the Cardiovascular System from Vitamin D", *Annals of Internal Medicine* (1966) at E648-E653 and Seelig, "Vitamin D and Cardiovascular, Renal, and Brain Damage in Infancy and Childhood, *Annals New York Academy of Sciences* (1969) at E664-E691.

** In his affidavit the Commissioner noted: "These high potency vitamin A and D preparations provide excessive amounts of the vitamins which are useless as a food for virtually anyone unless he is suffering from a serious disease condition, in which case carefully selected quantities of vitamin(s) are used as part of the total therapy of the patient." (385a).

tion. The recent amendments to the Act are to the same effect. Judge Mansfield's discussion of objective intent demonstrates that the absence of a nutritional or food use remains a relevant, and important, consideration: "Measuring intent on an objective basis, as it must be, he [the Commissioner] may have concluded that in view of the extremely small percentage used for nutritional purposes Vitamins A and D at higher dosage levels were intended for use in the 'cure, mitigation, prevention or treatment of disease'." (314a).

Beginning with Vitamin A, there was ample record ** support for the absence of a nutritional use for more than 10,000 IU of that vitamin per day:

> The recommended daily allowances of vitamin A are: for infants and children up to age 12 years, from 1,500 to 4,500 I.U.; for adults, 5,000 I.U.; and for pregnant women 6,000 I.U. Although diets of many individuals provide higher levels of vitamin A, there are no known advantages in exceeding these allowances in normal individuals. (E 365).
>
> * * * * *
>
> The adult daily requirement for optimum nutrition according to the National Research Council is 5000 units. During pregnancy and lactation the requirements are probably 50 per cent greater. . . . As can be seen, there is real danger of toxicity from protracted use of large doses, and when one deviates from the officially recommended dose one must watch for this. (E 287).

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* On April 9, 1976, the defendants filed with the District Court an extensive memorandum on the evidence in the record with respect to the classification of these vitamins as drugs. Because of the limitation on brief length we have here restricted our quotations from the record. More extensive citations and quotations appear in the memorandum filed with the District Court.

Additionally, the need for increased dosages of vitamin A was linked to impaired fat absorption and diabetes. (E238 and E268).

Thus, in contrast to the record before Judge Friendly, which showed that "a significant number of persons have indisputable nutritional need for potencies exceeding the upper limits" of U. S. RDA's, 504 F.2d at 789, the record here is clear that there is no nutritional need for vitamin A in excess of the U. S. RDA for healthy persons.* Persons with diseases, such as diabetes, which impair fat absorption may need additional vitamin A. But in that situation, the additional vitamin A is used to treat or mitigate a disease and is a drug within the meaning of the statute.

There is similar record support for the conclusion that there is no nutritional need for vitamin D in excess of 400 IU per day. The National Academy of Sciences, Food and Nutritional Board, National Research Council in establishing the Recommended Dietary Allowances (RDA's) made** these observations about the need for vitamin D:

> Vitamin D is required throughout the growth period, as evidenced by the rare occurrence of vitamin D deficiency rickets in adolescents. . . . *In the past, the recommended intake for children and adolescents has been 400iu/day, and this is re-*

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* Plaintiffs attempt to paint the administrative record as containing support for widely differing views on the nutritional needs of persons for vitamins A and D is an obvious failure. Plaintiffs cite only one comment in the administrative record, that of Linus Pauling, to support their position.

** The U.S. RDA's are based upon The National Academy of Science's recommended dietary allowances.

affirmed here. Ingestion of this amount of vitamin D protects practically all normal children from deficiency, and there is no evidence that this intake is harmful in any way. . . .

The requirement of vitamin D in adult life is not known. The occurrence of deficiency states (though very rare) indicates that a small need exists, but *it is considered that the amounts required are so small that under normal circumstances they are met by the vitamin D content of the usual mixed diet and by exposure to sunlight.* For persons working at night, and for nuns and others whose clothing or customs shield them from sunlight, the regular consumption of vitamin D-fortified milk is recommended.

The requirement for vitamin D during pregnancy and lactation also is not known. On the basis of the small amount of evidence, *a daily intake of 400 IU is recommended during pregnancy and lactation.* (Emphasis added) (59a).*

See also E 408 and the comment received from the University of Liverpool. (197a).

Furthermore, the record indicates that only those persons with medical problems causing poor vitamin D and/or fat absorption need more vitamin D. Acting upon a comment from the American Academy of Pediatrics (194a, and specifically referred to in the preamble (38 Fed. Reg. 20724; 33a)), the regulation was revised to permit the sale of foods, which are represented to be

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* This publication was Exhibit "C" to the affidavit of Robert Ullman, filed in support of plaintiffs' motion for a preliminary injunction and was referred to at 37 Fed. Reg. 26619 when the rule was proposed. (36a).

used only under medical supervision, to contain up to 1000 units of vitamin D. The comment read in part:

> The Committee on Nutrition recommends that Vitamin D in amounts up to 1000 I.U. be allowed without prescription in foods for special dietary use for specific medical problems—in this instance foods, designed for dietary management of subjects with poor Vitamin D absorption and steatorrhea or fat malabsorption.
>
> Considerable evidence exists that there is Vitamin D deficiency leading to osteomalacia associated with steatorrhea. Providing Vitamin D in amounts up to 1000 I.U. for daily consumption in foods designed for patients with steatorrhea will provide some protection from Vitamin D deficiency and entails no risk of Vitamin D excess. This exception is requested only for special foods and not for vitamin and mineral supplements because the latter may be used in excess, whereas the foods cannot be taken in great excess. (194a)

This modification of the vitamin D regulation exemplifies Judge Mansfield's suggested distinction between the Vitamin A and D regulations and the general vitamin regulations under review in *NNFA* v. *FDA*, *i.e.*, more particularized analysis and differing levels of regulation.

In sum, this is not a case like the one before Judge Friendly in which the record supported a good faith sale for non-therapeutic purposes at the level of drug classification. The record amply supports the conclusion that there is no nutritional need for Vitamins A and D at the regulated levels. Moreover, the Commissioner of Food and Drugs has stated in his affidavit that in his judgment a seller of these high potency products knows or should know that they are *not* food products, *i.e.*, that a seller

"knows or should know that his product is likely to be used by purchasers hoping for some therapeutic benefit such as deliverance from cirrhosis, acne, psoriasis or arthritis" (381a). The Commissioner of Food and Drugs has been a practicing physician and medical school dean (379a). His statements based on his experience should not be dismissed lightly (312a, n.11)

(2) The therapeutic usage of vitamins A and D.

In paragraph 5 of his affidavit, Commissioner Schmidt attested to his knowledge that these vitamins at the regulated levels are used for therapeutic purposes. (380a-381a). The contemporaneous record was replete with evidence of the therapeutic use of vitamin A by physicians and by lay people. Unfortunately, the lay use is often associated with and is the cause of vitamin A intoxication. Turning to the clinical evidence of therapeutic use, we refer the Court to the following record references:

> Apparently on an empirical basis, 1000 to 500,000 I.U. daily have been advised in treatment or prophylaxis of the common cold, acne, a variety or dermatoses with particular selection of those exhibiting hyperkeratosis, ocular diseases manifesting themselves by night blindness or corneal degeneration, and sometimes in otologic, gynecologic, renal, and enteric disorders. (E 271)

See also, E 238, E 327.

Similarly, the record is replete with evidence of lay use of vitamin A for therapeutic purposes. An examination of the cases reported in the record literature reveals the circumstances which led to the consumption of the toxic quantity. Children are often the unwitting victims of their parents' or grandparents' efforts to cure or pre-

vent diseases. One article discussed seven cases of overdose involving infants and children and described the reasons for the parental treatment. (E 173). Other reviews of infant overdose cases drew like conclusions. (E 150, E 267, E 208, E 213 and E 308).

In cases involving adults, one physician reviewed prior case histories and described the circumstances leading to the excessive ingestion of vitamin A as follows:

> "Chronic hypervitaminosis A occurs in patients who have received large doses of this vitamin for dermatologic conditions and who have continued subsequent intake without medical supervision, and in food faddists who include large doses of various vitamin preparations in their daily dietary regimens." (E 310).

There was further support in the record for the Commissioner's conclusion that persons consumed vitamins under the mistaken belief that "if one was good, two were better" with a view to prevention and treatment of disease. *See*, E 217, E 245, E 309, E 366.

Again as with vitamin A, the record contains both evidence of clinical use of vitamin D and lay use of the vitamin for therapeutic purposes.

> Vitamin D has been used in the treatment of arthritis, allergy, rickets, psoriasis, acne, trichinosis and hypocalcemic states. (E 554)

Documented evidence showed lay use of vitamin D for the treatment of arthritis (E 398), rickets (E 450-E 451), and to prevent winter colds [Taylor, "Renal Caluli and Self-Medication with Multivitamin Preparations Containing Vitamin D", *Clinical Science* (1972), attached to a comment, (199a-206a)].

For both vitamins A and D the comments submitted by consumers expressed a desire to take these vitamins for therapeutic reasons (*e.g.* 581a-612a).

(3) Toxicity:

We submit that toxicity is a proper factor for the Court to consider in determining whether vitamins are drugs or foods. We believe that Judge Friendly's reference to the District Court's earlier decisions on the A and D regulation at 504 F.2d at 788, fn. 33, was an approving one. Moreover, the objective evidence which Judge Friendly suggests may be used to pierce a manufacturer's subjective claims of intent would logically include information contrary to those claims, such as the toxicity of an item sold as nutritional. Moreover, it would hardly make sense to recognize that the Commissioner may take into account a variety of factors in setting a prescription level short of the toxic level, and not permit the use of a similar margin of safety in classifying an item as a drug. (512 F.2d at 704).

Plaintiffs' argument that toxicity cannot be considered proceeds on an erroneous assumption that a product must be either a food or a drug and thus that if the item has food properties and is found to be toxic it must be declared an adulterated food and taken off the market pursuant to the food provisions of the Act. This assumption is simply incorrect, as the quotation by plaintiffs from the legislative history of the Act (Appellants' Brief at 8) makes clear. Numerous cases establish that the same article can be a food and can also be classified as a drug: the definitions are not mutually exclusive when the drug definition of Section 201(g)(1)(B) is applicable. (*Cf.* 201(g)(1)(c)). *E.g.*, *United States* v. *Vitasafe Corp.*, 345 F.2d 864 (3d Cir.), *cert. denied*, 382 U.S. 918 (1965). Thus, the fact that these high potency preparations of

vitamins A and D might, hypothetically, also be adulterated food preparations is no defense to FDA's conclusion that they are prescription drugs. (See 388a-389a).

We do not disagree with plaintiffs' observation that a central factor in determining the category for a preparation is the purpose for which the item is to be utilized. *See, e.g., Kordel* v. *United States*, 335 U.S. 345 (1948). However, we vigorously disagree with plaintiffs' assertion that the toxicity or potentiality for harmful effect has "no relationship" to the question of its intended use. (Appellants' Brief at 14). There would seem to be a common sense distinction between food and poison. In addition, we submit that, even if, *arguendo*, these vitamins could be regulated either as food or as drugs, it is for the Commissioner to make the decision as to which classification best serves the purposes of the Act. *CIBA Corp.* v. *Weinberger*, 412 U.S. 640, 643-44 (1973); *Bradley* v. *Weinberger*, 483 F.2d 410, 416-17 (1st Cir. 1973).

The medical articles in the record are most often case histories of toxic overdoses of vitamins A & D. In the *A.M.A. Journal of Diseases of Children* to which we referred the Court, there is a charted summary of the reported cases of vitamin A intoxication at pages E261-262. A similar chart of adult cases of hypervitaminosis A, including the reason for the consumption of the vitamin and the consequent symptoms, appears at E284-285. Another chart of the symptoms resulting from overdoses of vitamin A is on page E340. As noted earlier, these overdose cases were often related to efforts at self-medication. *See also*, E196, E233.

The toxicity hazards of Vitamin D are described in detail in the Taussig and Seelig articles to which we referred the Court. Other articles in the bibliography tell of deaths which resulted from excessive intake of vitamin D. (E 398-401, E 495-502).

Similarly, the medical articles report a tragic experience in the United Kingdom, where increased Vitamin D fortification of infant foods caused a sharp rise in the incidence of hypercalcemia. (E477, E551). In its mild form, this disease causes loss of appetite, vomiting and constipation. In its severe form, the consequences included dwarfism, mental retardation and osteosclerosis. (E474, E478 and E551). It is believed by some that the effects on infants were caused by the vitamin D intake by pregnant women. (E611).

Another frequent theme in the medical literature on vitamin D toxicity is that individual susceptibility and sensitivity to intake of vitamin D varies greatly, thus making the margin of safety very narrow. (E477-78, E533, E555, E568, E665).

In short, as this Court has previously noted: "There was ample evidence before the FDA that Vitamins A and D, when consumed in large quantities over a period of time, can be acutely toxic." (315a).

(4) The Ready Availability of the Vitamins in Medicinal Form.

Another factor considered by the Commissioner was the ready availability of these vitamins in medicinal form:

> The concern of the Food and Drug Administration is the availability of vitamin A and vitamin D in large dosage units in medicinal forms, i.e. capsules and tablets, particularly in view of the multiplicity of other sources of this vitamin in the daily diet. The convenience of ingestion in this form on a routine basis encourages excessive intake of these vitamins far beyond the average amounts ingested in normal diets of conventional food over extended periods of time. (38 Fed. Reg. 20724, col. 2.) (33a)

Here again, the regulations at issue in this case are significantly different from those under review by Judge Friendly, *i.e.*, the regulations under review by Judge Friendly applied to the addition of vitamins to any food product (breakfast cereals, milk, etc.)—not just to easily overdosed "medicinal forms" such as capsules and tablets.

(5) The Use and Promotion of Vitamins A and D as Drugs:

Apart from the total absence of a record showing a nutritional use for these high potencies of vitamins A and D, taking the publications in the Federal Register as a whole there can not be any serious question that the Commissioner was concerned in these regulations with the use and promotion of these dosages of vitamins A and D as drugs. Very specifically, in response to a comment that these regulations might have the effect of decreasing the consumption of vitamin D for nutritional purposes, the Commissioner states that the current proposal "is directed only at the use of vitamin D as a drug." 38 Fed. Reg. 20725, col. 1. (34a). Given the tandem treatment of vitamin A with D, it is an obvious conclusion that, if asked, the Commissioner would have responded the same way for vitamin A (*See, Bunny Bear, Inc.* v. *Peterson*, 473 F.2d 1002 (1st Cir. 1973), permitting reasonable common sense inferences to be drawn from the record in an informal agency rulemaking proceeding). In the initial proposal the Commissioner discussed vitamin A therapy in the treatment of acne (37 Fed. Reg. 26619, col. 1) (36a). In both the initial proposal and the final promulgation of the regulation the Commissioner referred to the widespread promotion of these vitamins for therapeutic purposes (37 Fed. Reg. 26618, col. 3) (35a); 38 Fed. Reg. 20724, col. 1 (33a). *See also*, Commissioner Schmidt's affidavit, ¶ 5 (379a-381a).

D. Vitamins A and D received detailed and specific consideration.

One of the distinguishing factors between this case and *NNFA* v. *FDA* suggested by Judge Mansfield was that the Food and Drug Administration gave particular and detailed consideration in the case at bar to the proper treatment for Vitamins A and D, in contrast to the across-the-board drug classification before Judge Friendly, which involved a single rule for nineteen vitamins and minerals.

Plaintiffs contend that no such treatment was afforded Vitamins A and D. It is, of course, readily apparent from the very fact of prescription regulation of Vitamins A and D that the Commissioner determined that they could not be treated just like any other vitamin. The Commissioner's concern derived from the fat solubility of these vitamins and their related toxicity. (390a). Among the common popularly used vitamins these characteristics in combination are unique.

Nor were the prescription levels set at the same point used in *NNFA* v. *FDA*. Focusing on the Vitamin A needs for most adults, which we suggest is a more meaningful comparison, the prescription level for Vitamin A is twice the recommended U.S. RDA level in *NNFA* v. *FDA*. (10,000 IU as compared to 5,000 IU). The 8,000 IU level to which reference is made is the amount needed by pregnant and lactating women. The regulated level for Vitamin D was set with a view to its slim margin of safety:

> There are significant numbers of individuals who are hyperreactive to excess Vitamin D. Generally, the margin of safety between nutritional requirements and toxic levels is small for Vitamin D. The margin is particularly small in those in-

dividuals who are hyperreactive. (37 Fed. Reg. 26619) (391).*

In addition, the Commissioner made special provision [21 C.F.R. § 3.95(d); now recodified as 21 C.F.R. § 250.110 (d)] for foods to be sold under medical supervision to persons with poor Vitamin D absorption, after comments were submitted on this particular subject (38 Fed. Reg. 20724) (395a). (See discussion, *supra*, at pp. 38-39).

Perhaps the best indication of the detailed and specific consideration given Vitamins A and D is the record support for the levels at which these vitamins have been classified as a drug and regulated under the prescription statute. After determining the nutritional level, the next questions are: (1) what is the lowest level of intake that has actually resulted in harm; and (2) what are the lower dosages of the pill which were the "culprit" in overdose cases.

In the case of Vitamin A, the Commissioner had before him evidence that the ingestion of as little as 25,000 ** units of vitamin A could cause serious effects as well as substantial evidence that 25,000 to 50,000 unit capsules of vitamin A were involved in cases of vitamin A overdone.*** In addition, many physicians cautioned against the ingestion of any quantity of vitamin A in excess of

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* As noted above at p. 46 there was ample record support for this concern.

** "Ingestion of as little as 25,000 to 50,000 I.U. of vitamin A per day for as short a period as 30 days can induce signs of increased intracranial pressure. Nonspecific findings encountered at all ages include dry skin and mucous membranes, sparse hair, brittle nails, myalgia, bone pain, arthralgia, abdominal pain, splenomegaly and hypoplastic anemia with leukopenia." (E365) (The Joint Committee Statement of the Committees of Drugs and Nutrition of the American Adademy of Pediatrics). *See also*, E176, E268, E291.

*** *See* E220, E225-226, E300, E399.

the recommended daily allowances.* Moreover, the record amply supports the conclusion that people consume multiple quantities of the high dosage capsules available on the market, a factor which this Court has found could be considered by the Commissioner. (315a). In light of all these circumstances, there was little choice for the Commissioner but to set the prescription level at 10,000 units. Twenty-five thousand unit capsules were involved in toxic overdoses. And any level significantly above 10,000 units would, if taken twice, exceed 25,000 units.

Turning now to the particular level at which the Commissioner determined that vitamin D shall be sold only on prescription, the considerations in that choice were summarized when the rule was first proposed. They were:

> . . . the toxicity of vitamin D, the possibility of severe irreversible adverse effects in some instances, and the narrow margin of safety . . . (37 Fed. Reg. 26619) (391a).

Again, with respect to vitamin D, we would submit that the Commissioner's decision to regulate vitamin D in excess of 400 units as a prescription drug was fully supported by the record before him. As discussed earlier, the record not only showed no nutritional need for more than 400 units of vitamin D, but also showed that most adults need either no dietary supplementation of vitamin D or considerably less than 400 units. While children require 400 units, that amount is generally included in their milk or formula and remains available without prescription.

Also, there was considerable evidence in the record that toxic doses of vitamin D were only slightly above

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*E365-366 and Comment of Dr. Mann of Vanderbilt University. (196a).

prophylactic ones. Included in the medical articles referred to in the bibliography was a review of sixteen cases of idiopathic hypercalcemia in infants administered supplemental intakes of 400 to 1600 units per day, with an average supplementation of 800 units (E377-E388), and a report of a 9 month old boy who consumed a 400 unit fortified milk formula and a 1000 unit supplementation and who had "severe idiopathic hypercalcemia associated with supravalvular aortic stenosis and valvular and post-valvular pulmonary stenosis". (E613-E615)*

It was undisputed that individual sensitivities to vitamin D vary greatly making for a very narrow margin of safety. Understandably the medical articles contained cautionary advice. (E493, E568 and United Liverpool Hospital Comment at 197a-198a). In short, there was no reason in the record to set the drug prescription level above 400 units and every reason to set it at that level.

In sum, the FDA properly classified vitamins A and D at the regulated levels as drugs. Applying subsection (A) of the drug definition, even as limited by *NNFA* v. *FDA*, vitamins A and D are drugs because the regulated levels exceed the nutritional levels in the USP and the NF. Applying subsection (B) of the drug definition, at these high dosage levels vitamins A and D are objectively "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." First, the record establishes the absence of a nutritional use for these vitamins at the regulated levels. Second, the record evidences the therapeutic uses of these vitamins. Third, the record establishes the toxic properties of these vitamins;

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* A comment from the Department of Pathology, the United Liverpool Hospitals, implicated 500 IU of vitamin D in hypercalcinuria (197a-198a, and referred to at 38 Fed. Reg. 20724, 395a).

the ready availability of these vitamins in medicinal form and their promotion as drugs. Lastly, the record supports the detailed consideration of these two vitamins and the appropriateness of the Commissioner's choice of the regulatory levels.

CONCLUSION

The decision below should be affirmed.

Dated: New York, New York
December, 1976

Respectfully submitted,

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State of New York)
County of New York) ss

Marian J. Bryant being duly sworn, deposes and says that she is employed in the Office of the United States Attorney for the Southern District of New York.

That on the 10th day of December, 1976 she served ~~a~~ two copies of the within Appellee's Brief

by placing the same in a properly postpaid franked envelope addressed:

Bass, Ullman & Lustigman, Esquires
747 Third Avenue
New York, New York 10017

And deponent further says she sealed the said envelope and placed the same in the mail chute drop for mailing in the United States Courthouse Annex, One St. Andrews Plaza, Borough of Manhattan, City of New York.

Marian J. Bryant

Sworn to before me this
10th day of December, 1976

PAULINE P. TROIA
Notary Public, State of New York
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Qualified in New York County
Commission Expires March 30, 1978